REMARKS/ARGUMENTS

In view of the amendments and remarks herein, favorable reconsideration and allowance of this application are respectfully requested. By this Amendment, non-elected claims 22, 23, 32 and 33 have been canceled without prejudice or disclaimer. In addition, claims 2 and 19 has been canceled herein without prejudice or disclaimer. In addition claims 1 and 5 have been amended to more clearly distinguish the prior art of record.

Applicant notes, with appreciation, that the Examiner has indicated that claims 13, 24 and 29 are directed to allowable subject matter and would be allowed if amended to independent form. As an initial matter, Applicant points out that claim 29 is presently in independent form and, therefore, is believed to be in condition for formal allowance. Inasmuch as Applicant believes that all of the claims are now in condition for allowance, claims 13 and 24 have not been amended to independent form at this time.

The Examiner contends that claims 1-3, 8-11, 18 and 34 of the present application lack novelty in view of US 5,417,666 (Coulter). For at least the following reasons, Applicant respectfully submits that the present claims are not anticipated by Coulter. Thus, reconsideration and withdrawal of this rejection are respectfully requested.

In the Examiner's own words:

"Coulter teaches a catheter system with one embodiment teaching an ***interior cover (5) for a cannula (4)*** *and another embodiment teaches an* ***external cover (15) for a cannula (14)****. The cover is removed after the device has been inserted in the patient."*

Having reviewed the specification and drawings of Coulter, we note that interior and external covers disclosed therein, and indicated in the drawings by numerals (5) and (15), respectively are, in fact, not described as covers for a cannula. Rather, these covers serve to protect the interior or external surface of a "semi-rigid funnel member" (e.g. column 4, line 29). Furthermore, it is clear from the description that said funnel member constitutes part of a sheath assembly and not a catheter or cannula:

*"...includes a sheath assembly **2** through which a conventional catheter **12** of appropriate outer diametrical dimensions is introduced into the bladder (not shown), past the contaminated zone **13** in the urethra **11**"*

(Column 4, lines 24-27.)

and:

*"Figure **1** illustrates a sheath assembly **2** which comprises a semi-rigid funnel member **4** and a flexible cover member **5**."*

(Column 4, lines 28-30.)

It is thus clear from the above-quoted passages that the cover disclosed in Coulter is part of a sheath assembly, the purpose of which is to permit the production of a sterile intra-urethral zone prior to insertion of a physically-separate catheter. In other words, the function of the prior art cover is to prevent contamination of the catheter at the time of its insertion and at that time only. In contrast, the function of the cover of the present invention is to permit removal of biofilm build-up during prolonged use of the indwelling device.

Furthermore, in view of the usual meaning of the term "cannula" as understood by the skilled artisan in this field, we do not believe that either the abovementioned funnel-shaped member or the sheath assembly of which said member forms an integral part could be fairly described by said term. To this end, the Applicant respectfully directs the Examiner's attention to the definitions of the term "cannula" found in two widely-respected dictionaries of the English language:

"A flexible tube, usually containing a trocar at one end, that is inserted into a bodily cavity, duct, or vessel to drain fluid or administer a substance such as a medication."

(The American Heritage Dictionary of the English Language, 4th edition, 2000.)

"A small tube of metal, wood, or India rubber, used for varioius purposes, esp. for injecting or withdrawing fluids. It is usually associated with a trocar."

(Webster's Revised Unabridged Dictionary, 1998.)

[Both of the above-quoted dictionary definitions may be found at the following web site:

http://dictionary.reference.com/search?q=cannula]

In conclusion, the Applicant respectfully submits that the above-discussed funnel member-cover disclosed by Coulter is clearly very different from the invention disclosed in present claim 1, which is directed to a "medical device for insertion into a body", wherein said device itself is covered by at least one detachable cover. Thus, in the case of the present invention, the cover is a cover for a medical device, while in Coulter, the

cover is a cover for a separate member that is used as an insertion tool permitting the insertion of a medical device into a sterile zone. The Applicant further submits that the funnel-shaped member (or sheath) could not be fairly be described as a "medical device", according to the commonly-held understanding of that term. Furthermore, the present application explicitly provides a list of examples of entities which may be considered "medical devices":

"These include, for example, various types of catheters, cannulae, drains, implants, stents, pacemakers, electrodes and other devices."

(Page 1, lines 6-8.)

While this is clearly a non-exhaustive list, all of its members clearly have in common the feature of being primary devices in the sense that they are all capable of directly fulfilling a particular medical or surgical requirement (e.g. insertion or withdrawal of fluids, enlargement of an intravascular space, regulation of electrical activity in the heart). In contradistinction, the funnel member disclosed by Coulter is a secondary device in that its sole purpose is to assist in the sterile insertion of a specific primary device, namely a catheter.

In order to further emphasize the difference between Coulter and the present invention with respect to the location, function and use of the cover(s), Applicant has amended claim 1 to recite the list of medical devices of canceled claim 2.

In view of the foregoing explanations and claim 1 amendment, Applicant respectfully requests that the examiner withdraw the rejection of claims 1-3,8-11,18 and 34 over Coulter.

The examiner has rejected claims 1,2,3,8-10, 12,15,16,31 and 4 as being anticipated by US 5,571,172 (Chin). The basis for this rejection is the examiner's contention that:

"Chin teaches a cover for a medical device such as a stent (column 4, line 45) wherein the cover has a row of perforations allowing for easy removal from the device after the system has been inserted into the patient. The perforations on the cover create a rough surface."

Following review of the cited document, however, Applicant submits that the invention disclosed therein is limited to a sheathed graft, preferably for use in endoscopic aortofemoral bypass grafting. The Applicant respectfully directs the examiner's attention to the fact that Chin's disclosure is limited to a sheathed graft for use in an intravascular grafting method, rather than the more general "cover for a medical device". Furthermore, in view of the present amendment to claim 1, grafts or implants having detachable covers, as disclosed by Chin, do not fall within the scope of the present invention as claimed. The Applicant thus respectfully requests that the examiner withdraw the rejection of the above-enumerated claims in view of Chin.

Claim 19 is rejected by the examiner as being anticipated by US 2002/0120324 (Holman *et al.*) for the following reasons:

"Holman et al. teaches a cover for a stent that is helically wound over the device and may be used by itself or as an inner or outer sleeve [0133]. The helical cover is removed by unwrapping the strip [0141]."

There exist several structural differences between the covered stent described in the above-referenced passages of Holman and the embodiment of the present invention claimed in present claim 19. However, in order to expedite allowance of the remainder of the claims, Applicant respectfully has canceled, without prejudice, claim 19 from the present application. Thus, withdrawal of this rejection is respectfully requested.

The examiner contends that present claims 5-7 are unpatentable for the reason that they are obvious over one embodiment disclosed in US 5,417,666 (Coulter) in view of another embodiment disclosed in Coulter. More specifically, the examiner combines one embodiment of Coulter, wherein the cover is on the interior surface of the funnel-shaped member, with a second embodiment in which the cover is located on the exterior surface of said member. According to the examiner:

"It would have been obvious to one skilled in the art at the time of the invention to incorporate the use of both covers at the same time in order to keep all surfaces of the device sterile."

The Applicant respectfully directs the Examiner's attention to the fact that, as explained hereinabove, Coulter discloses an invention comprising an insertion-assisting device bearing a cover, rather than a catheter, cannula or other device specifically named in amended claim 1, onto the surface of which is attached one or more covers. In view of

the fact that Coulter's invention could not fulfill the primary objective of the present invention (namely removal of biofilm build up during use of an indwelling device) the Applicant respectfully contends that the embodiment of the present invention defined in present claims 5-7 would not be obvious over the combination of the internally- and externally-covered embodiments of the Coulter.

However, in order to further emphasize the non-obvious nature of the embodiment defined in the rejected claims, and in order to expedite allowance, claim 5 has been amended herein.. It will be seen from this amendment, and from the supporting passage of the description (page 3, lines 8-20) that the clear intention of this embodiment of the present invention is that the multiple covers are arranged in a circumferential, "onion-skin" manner. Thus, the clearer definition of the disposition of the various cover layers that is given in amended claim 5 serves to further distinguish the embodiment defined in that claim from the two layer internal cover-external cover combination synthesized by the examiner from the chosen combination of prior art embodiments.

In view of the above, reconsideration and withdrawal of this rejection is respectfully requested.

The examiner has rejected claims 17 and 30 as being obvious over Coulter in view of US 5,188,606 (Maloney *et al.*). The rejected claims, both of which are dependent on claim 1, recite a blade or cutter as a technical feature of the claimed medical device.

In responding to this rejection, the Applicant directs the examiner's attention to the above-recited arguments and explanation regarding the significant differences between

Coulter and the present invention. Thus, while it is true that several prior art publications (including Maloney *et al.*) describe the use of cutting blades as part of intravascular medical devices, the Applicant respectfully contends that the skilled artisan would not find dependent claims 17 and 30 obvious in view of the combination of Coulter and Maloney *et al.* This is for the reasons that, firstly, neither of said publications provide any teaching for the specific medical devices defined in amended claim 1, and secondly, that neither publication provides any general teaching that would guide the reader to providing a solution to the biofilm product buildup problem that is successfully solved by the present invention. The Applicant therefore respectfully requests that the examiner reconsider and withdraw this rejection.

The examiner has rejected claims 14,20,21,25 and 26 as being obvious over Coulter in view of US 2002/0120324 (Holman *et al.*). Each of these dependent claims defines a device according to claim 1, further characterized by possessing one of the following technical features: reversible attachment of the cover by means of elastic forces, distally-placed ring, a cover in the form of joined inner and outer cylindrical shells, impermeability of the cover to microorganisms and to water.

While it is true that some of these extra technical features may arguably be taught by Holman *et al.*, there are (as explained hereinabove) significant structural and functional differences between the device of Coulter and that of the present invention. Consequently, the Applicant strongly contends that a combination of features taken from these two publications would neither suggest nor teach the devices defined in the rejected

claims. Thus, reconsideration and withdrawal of this rejection are also respectfully requested.

Claims 27 and 28 are rejected by the Examiner on the basis that the inventions defined therein are obvious over Coulter in view of US 3,598,127 (Wepsic).

The rejected claims define preferred embodiments of the device of claim 1 in which the cover stores and releases a substance (claim 27), more preferably an anti-microbial substance (claim 28). The Wepsic publication defines a catheter tube, the wall thereof comprising an inner, impermeable layer and outer slightly permeable layer, with repositories of antibacterial substances located at the junction of said two layers. In this way, the antibacterial substances are slowly released towards the outer surface of the catheter.

In view of the lack of relevance of Coulter (as explained at length above), the Applicant respectfully submits that a skilled artisan presented with both of the cited references would not arrive at a covered device fulfilling the structural and functional requirements of claim 1 that further comprises a store of antimicrobial (or other) fluid within or beneath the cover. The Applicant thus respectfully requests that the examiner withdraw this obviousness rejection.

In view of the foregoing amendments and remarks, Applicant believes that all of the pending claims are now in condition for allowance. Thus, withdrawal of the rejections and passage of this case to issuance at an early date are earnestly solicited.

Should the Examiner have any questions regarding this response, or deem that any formal issues need to be addressed prior to allowance, the Examiner is invited to call the undersigned attorney at the phone number below.

Respectfully submitted,

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